Complete Summary

GUIDELINE TITLE

Management of patients who have a history of penicillin allergy. Sexually transmitted diseases treatment guidelines 2006.

BIBLIOGRAPHIC SOURCE(S)

Centers for Disease Control and Prevention, Workowski KA, Berman SM. Management of patients who have a history of penicillin allergy. Sexually transmitted diseases treatment guidelines 2006. MMWR Morb Mortal Wkly Rep 2006 Aug 4;55(RR-11):33-5. [222 references]

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Centers for Disease Control and Prevention. Management of patients who have a history of penicillin allergy. Sexually transmitted diseases treatment guidelines. MMWR Recomm Rep 2002 May 10;51(RR-6):28-30.

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SCOPE

DISEASE/CONDITION(S)

Penicillin allergy in patients with sexually transmitted diseases

GUIDELINE CATEGORY

Evaluation
Management
Treatment

CLINICAL SPECIALTY

Allergy and Immunology
Family Practice
Infectious Diseases
Internal Medicine
Obstetrics and Gynecology
Pediatrics
Preventive Medicine

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Health Care Providers
Managed Care Organizations
Nurses
Physician Assistants
Physicians
Public Health Departments

GUIDELINE OBJECTIVE(S)

- To update the Sexually Transmitted Diseases Treatment Guidelines 2002 (*MMWR 2002;51[No. RR-6]*)
- To assist physicians and other health-care providers in preventing and treating sexually transmitted diseases (STDs)

TARGET POPULATION

Patients with sexually transmitted diseases who have a history of penicillin allergy

INTERVENTIONS AND PRACTICES CONSIDERED

1. Full battery of skin-test agents: major determinant benzylpenicilloyl poly-L-lysine (Pre-Pen®) and minor determinant precursors (benzylpenicillin G, benzylpenicilloate or penicilloyl propylamine)
    - Epicutaneous (prick) test
    - Intradermal test
2. Desensitization to penicillin (oral or intravenous)

MAJOR OUTCOMES CONSIDERED

Allergic reaction to penicillin

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Subjective Review

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Beginning in 2004, the Centers for Disease Control and Prevention (CDC) personnel and professionals knowledgeable in the field of sexually transmitted diseases (STDs) systematically reviewed evidence (including published abstracts and peer-reviewed journal articles) concerning each of the major STDs, focusing on information that had become available since publication of the *Sexually Transmitted Diseases Treatment Guidelines, 2002*. Background papers were written and tables of evidence constructed summarizing the type of study (e.g., randomized controlled trial or case series), study population and setting, treatments or other interventions, outcome measures assessed, reported findings, and weaknesses and biases in study design and analysis. A draft document was developed on the basis of the reviews.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus (Consensus Development Conference)

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

In April 2005, the Centers for Disease Control and Prevention (CDC) staff members and invited consultants assembled in Atlanta, Georgia, for a 3-day

meeting to present the key questions regarding sexually transmitted disease (STD) treatment that emerged from the evidence-based reviews and the information available to answer those questions. When relevant, the questions focused on four principal outcomes of STD therapy for each individual disease: 1) microbiologic cure, 2) alleviation of signs and symptoms, 3) prevention of sequelae, and 4) prevention of transmission. Cost-effectiveness and other advantages (e.g., single-dose formulations and directly observed therapy of specific regimens) also were discussed. The consultants then assessed whether the questions identified were relevant, ranked them in order of priority, and attempted to arrive at answers using the available evidence. In addition, the consultants evaluated the quality of evidence supporting the answers on the basis of the number, type, and quality of the studies.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

No proven alternatives to penicillin are available for treating neurosyphilis, congenital syphilis, or syphilis in pregnant women. Penicillin is also recommended for use, whenever possible, in human immunodeficiency virus (HIV)-infected patients. Of the adult U.S. population, 3%-10% have experienced an immunoglobulin E (IgE) mediated allergic response to penicillin such as urticaria, angioedema, or anaphylaxis (i.e., upper airway obstruction, bronchospasm, or hypotension). Re-administration of penicillin to these patients can cause severe, immediate reactions. Because anaphylactic reactions to penicillin can be fatal, every effort should be made to avoid administering penicillin to penicillin-allergic patients, unless they undergo acute desensitization to eliminate anaphylactic sensitivity.

An estimated 10% of persons who report a history of severe allergic reactions to penicillin remain allergic. With the passage of time after an allergic reaction to penicillin, the majority of persons who have had a severe reaction to penicillin stop expressing penicillin-specific IgE. These persons can be treated safely with penicillin. The results of many investigations indicate that skin testing with the

major and minor determinants of penicillin can reliably identify persons at high risk for penicillin reactions. Although these reagents are easily generated and have been available for >30 years, only benzylpenicilloyl poly-L-lysine (Pre-Pen® [i.e., the major determinant]) and penicillin G have been available commercially. Testing with only the major determinant and penicillin G identifies an estimated 90%-97% of the currently allergic patients. However, because skin testing without the minor determinants would still miss 3%-10% of allergic patients and because serious or fatal reactions can occur among these minor-determinant-positive patients, specialists suggest exercising caution when the full battery of skin-test reagents is not available. An additional challenge has occurred with the recent unavailability of Pre-Pen®; however, plans for future availability of this product have been made, as well as a companion minor determinant mixture.

Skin-test Reagents for Identifying Persons at Risk for Adverse Reactions to Penicillin

Major Determinant

- Benzylpenicilloyl poly-L-lysine (Pre-Pen® [Taylor Pharmacal Company, Decatur, Illinois]) (6×10^{-5}M).

Minor Determinant Precursors *(Note: Aged penicillin is not an adequate source of minor determinants. Penicillin G should be freshly prepared or should come from a fresh-frozen source.)*

- Benzylpenicillin G (10^{-2}M, 3.3 mg/mL, 6,000 units/mL)
- Benzylpenicilloate (10^{-2}M, 3.3 mg/mL)
- Benzylpenicilloate (or penicilloyl propylamine) (10^{-2}M, 3.3 mg/mL)

Positive Control

- Commercial histamine for epicutaneous skin testing (1 mg/mL)

Negative Control

- Diluent used to dissolve other reagents, usually phenol saline

Recommendations

If the full battery of skin-test reagents is available, including the major and minor determinants (see section on Penicillin Allergy Skin Testing below), patients who report a history of penicillin reaction and are skin-test negative can receive conventional penicillin therapy. Skin-test-positive patients should be desensitized.

If the full battery of skin-test reagents, including the minor determinants, is not available, the patient should be skin tested using benzylpenicilloyl poly-L-lysine (i.e., the major determinant) and penicillin G. Patients who have positive test results should be desensitized. Some specialists suggest that persons who have negative test results should be regarded as probably allergic and should be desensitized. Others suggest that those with negative skin-test results can be

test-dosed gradually with oral penicillin in a monitored setting in which treatment for anaphylactic reaction can be provided.

If the major determinant (Pre-Pen®) is not available for skin testing, all patients with a history suggesting IgE mediated reactions (anaphylaxis, angioedema, bronchospasm, or urticaria) to penicillin should be desensitized in a hospital setting. In patients with reactions not likely to be IgE mediated, outpatient oral desensitization or monitored test doses may be considered.

Penicillin Allergy Skin Testing

Patients at high risk for anaphylaxis, including those who 1) have a history of penicillin-related anaphylaxis, asthma, or other diseases that would make anaphylaxis more dangerous or 2) are being treated with beta-adrenergic blocking agents, should be tested with 100-fold dilutions of the full-strength skin-test reagents before being tested with full-strength reagents. In these situations, patients should be tested in a monitored setting in which treatment for an anaphylactic reaction is available. If possible, the patient should not have taken antihistamines recently (e.g., chlorpheniramine maleate or terfenadine during the preceding 24 hours, diphenhydramine hydrochloride (HCl) or hydroxyzine during the preceding 4 days, or astemizole during the preceding 3 weeks).

Procedures

Dilute the antigens either 1) 100-fold for preliminary testing if the patient has had a life-threatening reaction to penicillin or 2) 10-fold if the patient has had another type of immediate, generalized reaction to penicillin within the preceding year.

Epicutaneous (Prick) Tests

Duplicate drops of skin-test reagent are placed on the volar surface of the forearm. The underlying epidermis is pierced with a 26-gauge needle without drawing blood.

An epicutaneous test is positive if the average wheal diameter after 15 minutes is 4 mm larger than that of negative controls; otherwise, the test is negative. The histamine controls should be positive to ensure that results are not falsely negative because of the effect of antihistaminic drugs.

Intradermal Test

If epicutaneous tests are negative, duplicate 0.02 mL intradermal injections of negative control and antigen solutions are made into the volar surface of the forearm using a 26- or 27-gauge needle on a syringe. The crossed diameters of the wheals induced by the injections should be recorded.

An intradermal test is positive if the average wheal diameter 15 minutes after injection is >2 mm larger than the initial wheal size and also is >2 mm larger than the negative controls. Otherwise, the tests are negative.

Desensitization

Patients who have a positive skin test to one of the penicillin determinants can be desensitized (see Table 1 in the original guideline for an oral desensitization protocol). This is a straightforward, relatively safe procedure that can be performed orally or intravenously. Although the two approaches have not been compared, oral desensitization is regarded as safer to use and easier to perform. Patients should be desensitized in a hospital setting because serious IgE-mediated allergic reactions can occur. Desensitization usually can be completed in approximately 4 hours, after which the first dose of penicillin is administered. After desensitization, patients must be maintained on penicillin continuously for the duration of the course of therapy.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is not specifically stated for each recommendation.

Throughout the 2006 guideline document, the evidence used as the basis for specific recommendations is discussed briefly. More comprehensive, annotated discussions of such evidence will appear in background papers that will be published in a supplement issue of the journal *Clinical Infectious Diseases*.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Skin testing can reliably identify persons at high risk for allergic reactions to penicillin, which can sometimes be fatal.
- Desensitization allows penicillin-allergic patients to receive penicillin therapy.

Subgroups Most Likely to Benefit

- Patients with neurosyphilis, congenital syphilis, or syphilis in pregnant women, as there are no proven alternatives to penicillin available for treatment.
- Patients with HIV infection, for whom penicillin is recommended, whenever possible.

POTENTIAL HARMS

- Anaphylaxis can occur during skin testing in high-risk patients.
- Serious immunoglobulin E-mediated allergic reactions, although unlikely, can occur during desensitization procedures.

Subgroups Most Likely to be Harmed

Patients at high risk for anaphylaxis are those who have a history of penicillin-related anaphylaxis, asthma, or other diseases that would make anaphylaxis more dangerous or who are being treated with beta-adrenergic blocking agents.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- These recommendations were developed in consultation with public- and private-sector professionals knowledgeable in the treatment of patients with sexually transmitted diseases (STDs). The recommendations are applicable to various patient-care settings, including family planning clinics, private physicians' offices, managed care organizations, and other primary-care facilities.
- These recommendations are meant to serve as a source of clinical guidance: health-care providers should always consider the individual clinical circumstances of each person in the context of local disease prevalence. These guidelines focus on the treatment and counseling of individual patients and do not address other community services and interventions that are important in STD/human immunodeficiency virus (HIV) prevention.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Personal Digital Assistant (PDA) Downloads

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

IOM DOMAIN

Effectiveness
Safety

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Centers for Disease Control and Prevention, Workowski KA, Berman SM. Management of patients who have a history of penicillin allergy. Sexually transmitted diseases treatment guidelines 2006. MMWR Morb Mortal Wkly Rep 2006 Aug 4;55(RR-11):33-5. [222 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1993 (revised 2006 Aug 4)

GUIDELINE DEVELOPER(S)

Centers for Disease Control and Prevention - Federal Government Agency [U.S.]

GUIDELINE DEVELOPER COMMENT

These guidelines for the treatment of persons who have sexually transmitted diseases (STDs) were developed by CDC after consultation with a group of professionals knowledgeable in the field of STDs who met in Atlanta, Georgia, during April 19–21, 2005.

SOURCE(S) OF FUNDING

United States Government

GUIDELINE COMMITTEE

Not stated

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Centers for Disease Control and Prevention. Management of patients who have a history of penicillin allergy. Sexually transmitted diseases treatment guidelines. MMWR Recomm Rep 2002 May 10;51(RR-6):28-30.

GUIDELINE AVAILABILITY

Electronic copies: Available from the Centers for Disease Control and Prevention (CDC) Web site:

- HTML Format
- Portable Document Format (PDF)

Print copies: Available from the Centers for Disease Control and Prevention, MMWR, Atlanta, GA 30333. Additional copies can be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402-9325; (202) 783-3238.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Workowski KA, Levine WC, Wasserheit JN. U.S. Centers for Disease Control and Prevention guidelines for the treatment of sexually transmitted diseases: an opportunity to unify clinical and public health practice. Ann Intern Med. 2002 Aug 20;137(4):255-62. Electronic copies: Available through Annals of Internal Medicine Online.
- The CDC Sexually Transmitted Diseases Treatment Guidelines 2004 for PDA or Palm OS. Available from the CDC National Prevention Information Network (NPIN) Web site.

PATIENT RESOURCES

None available

NGC STATUS

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